

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
PENNSYLVANIA**

DANIEL HUBERT, individually and on behalf of all others similarly situated,	:	Civil Action No. 2:15-cv-01391-MRH
	:	
Plaintiff,	:	
	:	Oral Argument Requested
v.	:	
GENERAL NUTRITION CORPORATION,	:	This Document Relates All Actions
	:	
Defendant.	:	
	:	
(In re: GNC Picamilon/BMPEA Litigation)	:	

**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT'S REQUEST FOR
JUDICIAL NOTICE IN SUPPORT OF ITS MOTION TO DISMISS**

Plaintiffs, on behalf of themselves and members of the putative class, submit the following opposition to Defendant General Nutrition Corporation's ("GNC") Request for Judicial Notice in Support of its Motion to Dismiss ("Request for Judicial Notice"), Dkt. No. 49-5.

I. INTRODUCTION

Through Defendant's Request for Judicial Notice, it improperly seeks to have this Court decide disputed issues of fact in this case on its Motion to Dismiss First Amended Consolidated Complaint ("Motion to Dismiss" or "Mot."). Defendant asks this Court to take judicial notice of nine documents: (1) a U.S. Food and Drug Administration ("FDA") warning letter dated April 22, 2015 to Hi-Tech Pharmaceuticals, Inc. (attached as Exhibit C to the Declaration of Stephen Cherry ("Cherry Decl."), Dkt. No. 49-1); (2) a Department of Health and Human Services ("DHHS") Certificate of Free Sale dated April 15, 2015 and signed by Dr. Cara Welch (the "Certificate") (Cherry Decl., Ex. D); (3) the Declaration of Dr. Cara Welch filed in *State of Oregon v. General Nutrition Corporation*, Case No. 15CV28591, in the Circuit Court of the

State of Oregon for the County of Multnomah (the “Welch Declaration” filed in the “Oregon Action”) (Cherry Decl., Ex. E); (4) an FDA warning letter dated November 30, 2015 to SDC Nutrition, Inc. (Cherry Decl., Ex. G); (5) the October 22, 2015 complaint filed against Defendant in the Oregon Action (Cherry Decl., Ex. H); and (6) four documents available on the FDA’s website including three informational documents (attached as Exhibits J-K, M to the Declaration of Amy B. Alderfer (“Alderfer Decl.”), Dkt. No. 49-3) and Chapter 4-1-1 of the July 2012 “Regulatory Procedures Manual” (the “Manual”) (Alderfer Decl., Ex. L). For all of the reasons discussed herein, Defendant’s Request for Judicial Notice should be denied.

II. ARGUMENT

Defendant’s Request for Judicial Notice suffers from two overarching defects. First, judicial notice is only appropriate for facts that are not in dispute by the parties. Second, Defendant improperly seeks judicial notice of documents that were not integral to, or relied upon by Plaintiffs in, the First Amended Consolidated Class Action Complaint (“Complaint”). At bottom, Defendant is attempting to improperly use some of these documents to put facts before this Court to support its Motion to Dismiss. Defendant’s attempt to persuade the Court to improperly decide disputed issues of fact in its favor on this pleading motion should be denied.

A. The Parties Dispute the Accuracy or Interpretation of Certain of the Documents

Defendant bases its request for judicial notice on Fed. R. Evid. 201(b), which provides that a court “may judicially notice a fact that is *not subject to reasonable dispute* because it: (1) is *generally known* within the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy *cannot reasonably be questioned.*” (Emphasis added).¹ These stringent requirements exist because “[f]or all practical purposes, judicially noticing a fact is tantamount to directing a verdict against a party as to the noticed fact.” *LaSalle*

¹ Defendant does not argue that judicial notice is appropriate because any of the documents or facts at issue are “generally known within the trial court’s territorial jurisdiction.”

Nat'l Bank v. First Conn. Holding Group, L.L.C. XXIII, 287 F.3d 279, 290 (3d Cir. 2002). Here, Defendant seeks judicial notice of facts that are highly disputed by Plaintiffs, and therefore Defendant's interpretation of such facts in support of its Motion to Dismiss should not be judicially noticed.

While Plaintiffs accept the *existence* of the documents referenced in Defendant's Request, Plaintiffs do not concede the accuracy of much of the information contained in those documents and/or their significance to this case. Courts typically reject attempts to conflate these two concepts when the party is improperly using the judicial notice vehicle to decide disputed issues of fact in its own favor. *See, e.g., United States v. Onyenso*, No.12-CR-602 (CCC), 2015 U.S. Dist. LEXIS 77582, at *21 (D.N.J. June 16, 2015) (court declined to take judicial notice of regulation because its application to defendant was unclear and was "the subject of vigorous dispute between the parties."); *Trevino v. Merscorp, Inc.*, 583 F. Supp. 2d 521, 527 (D. Del. 2008) ("In general, documents may not be judicially noticed for the truth of the matters stated in them.") (quoting Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence § 201.12[3] (2d ed. 2008)). Because the parties dispute the contents of certain documents and/or their application to the facts of this case, they should not be judicially noticed.

B. Defendant Inappropriately Requests Judicial Notice of Documents Extraneous to the Pleadings

Defendant's Request for Judicial Notice also wrongly asks this Court to take notice of documents outside of the Complaint. In ruling on a motion to dismiss, a district court generally may not consider matters or documents extraneous to the pleadings. *See Angelastro v. Prudential Bache Securities*, 764 F.2d 939, 944 (3d Cir. 1985). An exception to the general rule is that a "document integral to or explicitly relied upon in the complaint" may be considered. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotations omitted); *see also In re Donald J. Trump Casino Securities Litigation-Taj Mahal Litigation*, 7 F.3d 357, 368 n.9 (3d Cir. 1993) (quoting *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993)) ("a court may consider an undisputedly authentic

document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.””). Defendant seeks judicial notice of documents and facts that are not integral to, or even discussed in, the Complaint.

Defendant largely seeks judicial notice of these documents in an attempt to contradict facts properly and plausibly alleged in the Complaint. But Plaintiffs' allegations of fact are to be taken as true at this stage of the litigation. *See Westmoreland Advanced Materials, Inc. v. Allied Mineral Prods.*, nos. 16cv0263, 16cv604, 2016 U.S. Dist. LEXIS 76801, at *5 (W.D. Pa. June 13, 2016). Therefore, Defendant's request that the Court take judicial notice of these documents is improper to the extent that Defendant uses the documents to contradict Plaintiffs' allegations with its own interpretation of such documents. Accordingly, even if the existence of these documents is not in dispute, Defendant cannot use the mechanism of judicial notice to decide disputed issues of fact in Defendant's favor on this Motion to Dismiss.²

C. The Following Documents Convey Facts in Dispute and/or Exist Wholly Apart from the Complaint

While the foregoing principles apply generally to the documents at issue, Plaintiffs individually address why certain of these documents should not be judicially noticed.

1. April 22, 2015 FDA Warning Letter to Hi-Tech Pharmaceuticals, Inc. and November 30, 2015 FDA Warning Letter to SDC Nutrition, Inc. (Cherry Decl., Exs. C and G).

Plaintiffs do not dispute the existence of these documents. However, Defendant seeks

² Notably, Defendant does not seek judicial notice of all documents it presents. For example, Defendant does not seek judicial notice of Exhibit F to the Cherry Declaration, purported to be a September 28, 2015 email from Oregon Senior Assistant Attorney General David Hart to Defendant's counsel in Oregon (but not to Cherry). Nor could it for two reasons. First, Cherry has no personal knowledge of this document. Second, the email was not mentioned or referred to in Plaintiffs' Complaint. Accordingly any reference to this email should be stricken.

Defendant also fails to seek judicial notice of Exhibit B to the Cherry Declaration, an April 9, 2015 article from the New York Times titled “Retailers to Stop Sales of Controversial Supplements.” Judicial notice cannot be taken of this article because the Complaint does not mention or rely upon it. Moreover, Defendant improperly attempts to enter into evidence its interpretation of the contents of the article. *See* Mot. at 10. Accordingly, any reference to this article should, likewise, be stricken.

judicial notice of these warning letters to definitively establish its interpretation of the warning letters. Defendant reads the warning letters as merely “threat[s of] enforcement actions (if [the] products are not voluntarily removed from market][,]” (Mot. at 1), rather than, as Plaintiffs contend, proof that the Ingredients were deemed illegal. Because Plaintiffs strongly dispute Defendant’s interpretation of the warning letters, judicial notice should be denied.³

2. April 15, 2015 DHHS Certificate of Free Sale (Cherry Decl., Ex. D)

Plaintiffs object to the Court taking judicial notice of the existence of the Certificate as it is outside the scope of Plaintiffs’ Complaint and not relied upon for their claims. Plaintiffs further dispute Defendant’s improper purpose for seeking judicial notice of the Certificate, namely to support Defendant’s assertion that the Certificate’s issuance is “inconsistent” with the Welch Declaration. Mot. at 7. In other words, Defendant seeks a ruling from the Court that the Certificate contradicts the Welch Declaration’s determination that picamilon is not a dietary ingredient under the Food, Drug and Cosmetic Act (“FDCA”). *See* Mot. at 7 (Certificate “*in essence* announce[s] to the world that the subject products are freely (and lawfully) available for sale in the U.S. . . . Thus, as of April 15, 2015, the FDA’s public position was that picamilon was (*at least impliedly*) a lawful dietary ingredient.”) (Emphasis added). Accordingly there is a clear dispute over the “significance of the contents” of the Certificate, and therefore its import is not subject to judicial notice.

3. FDA Webpage Entitled “Export Certificates” (Alderfer Decl., Ex. J)

Plaintiffs object to the Court taking judicial notice of this webpage because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. Plaintiffs also dispute Defendant’s interpretation of the webpage’s content. Defendant maintains that the

³ The Cherry Declaration also attaches, as Exhibit H, a March 7, 2016 FDA warning letter to Nubreed Nutrition Inc. which deems *acacia rigidula* a “new dietary ingredient” for which no new ingredient notification has been provided. *See* Cherry Decl. at ¶13. Defendant does not even attempt to argue that this letter should be judicially noticed; therefore it should not be. And to the extent that this Court considers judicial notice of this letter, it would not be proper for the same reasons as Exhibits C and G to the Cherry Declaration.

FDA's issuance of Export Certificates for the products at issue establishes that the FDA agrees with the product representations and that the Defendant is, therefore, immunized from civil liability as a result. *See* Mot. at 7 ("The Certificates *in essence* announce to the world that the subject products are freely (and lawfully) available for sale in the U.S.") (emphasis added). Plaintiffs, on the other hand, maintain that the FDA takes a contrary position in both its letters and declarations in the Oregon Action. Accordingly, there is a clear dispute over the "significance of the contents" of the statements on this webpage that precludes it from being judicially noticed.

4. Chapter 4-1-1 of Regulatory Practices Manual dated July 2012 (Alderfer Decl., Ex. L)

Plaintiffs object to the Court taking judicial notice of the existence of this chapter of the Manual because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. The significance of this document is also subject to dispute, as Plaintiffs do not agree with Defendant's attempt to defang the import of the warning letters by interpreting the Manual as providing that "warning letters simply communicate the agency's position on a matter without committing the FDA to an enforcement action." Mot. at 19. Accordingly, taking judicial notice of this document would be inappropriate.

5. FDA Webpage Entitled "Letter of Guaranty" (Alderfer Decl., Ex. M)

Plaintiffs object to the Court taking judicial notice of the existence of this webpage because it exists outside the scope of the Complaint and Plaintiffs do not rely upon it for their claims. Plaintiffs also dispute Defendant's apparent proffered legal conclusion that, according to this webpage, a "Letter of Guaranty" insulates sellers of products from civil liability. *See* Mot. at 22. For all of the reasons discussed at length in Plaintiffs' concurrently filed Opposition to Defendant's Motion to Dismiss, *see id.*, Section IV.D, a Letter of Guaranty at most exempts innocent retailers from criminal prosecution under the FDCA and does not immunize its recipient from civil liability or other consequences of selling misbranded food. Accordingly, this document also cannot be judicially noticed.

III. CONCLUSION

For the reasons discussed herein, Plaintiffs respectfully request that this Court deny Defendant's Request for Judicial Notice of the documents discussed herein.

Dated June 24, 2016

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